Press release

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THERMOLAST® M meets new VDI 2017 guideline for medical grade plastics
Waldkraiburg, August 2019

Clear guideline for medical grade plastics

Thermoplastic elastomers comply with new VDI guideline 2017

KRAIBURG TPE announces that its THERMOLAST® M compounds meet the requirements of the guideline 2017 for medical grade plastics (MGPs) passed by the Association of German Engineers (VDI) in July 2019. Intended as a guideline for manufacturers and users of plastics for medical products, the VDI guideline 2017 regulates the requirements qualified MGPs have to meet, from basic requirements to formulation consistency and change management through to withdrawal terms.

Twenty materials suppliers, users and appointed bodies had formed a guidelines committee (RA) to work on a common minimum standard for MGPs, as there had previously been no clear guidelines or standards in the EU and the USA relating to the polymers used in this vital field of application – despite the Drug Master Files (DMF) issued by the Food and Drug Administration (FDA) in the USA and the ISO 10993 standard for the biocompatibility certification of medical products (including implants, in vitro diagnostic agents and pharmaceutical packaging), as well as the EU Regulation MPV 2017/745 on medical products that will become binding from May 2020.

“The VDI 2017 is an important first step toward harmonizing the range of performance that a medical grade plastic must fulfill, and it creates obligatory guidance in the communication between manufacturers of MGPs and OEMs and/or the manufacturers of medical, pharmaceutical and in vitro products,” says Oliver Kluge, a member of the guidelines committee and advisor for medical products at KRAIBURG TPE. “The new guideline explicitly provides scope for the respective materials suppliers and their customers to make broader arrangements.”

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Press release

One of the main consequences of VDI 2017 is a restriction of the range of raw materials and auxiliary agents permitted for MGPs, which means that some manufacturers are having to adjust their materials formulations. The new guideline also regulates the controlled continuity of the composition of specific compounds based on a documented change control management system, which ensures that the compounds are suitable for use for a long-term period and makes costly checks unnecessary. The VDI 2017 also allows for longer transition periods for withdrawn materials, thus providing more supply security to users.

“Our established thermoplastic elastomers from the THERMOLAST® M family – for medical use – have for a long time been complying with the requirements for MGPs that are now codified, so that we only need to flesh out some of the specifications,” Kluge explains. “But we will continue to actively work on future revisions of the guideline in order to further enhance the secured profile of MGPs.” Against the background of the MPV 2017/745 mentioned above, the VDI 2017 Medical Grade Plastics guidelines committee is planning to revise the current version for the first time as early as in 2020. The set of rules was presented and discussed in great detail at the VDI conference on MGPs held in Berlin in early July 2019.

Broad range of certified medical grade TPEs

All THERMOLAST® M compounds are free from heavy metals, latex, PVC and phthalates and are manufactured exclusively on dedicated production lines and at the highest degree of purity. A number of select material types have been tested and certified according to USP Class VI (Chapter 88), ISO 10993-5 (cytotoxicity), ISO 10993-10 (intracutaneous irritation), ISO 10993-11 (acute systemic toxicity), and ISO 10993-4 (hemolysis). The quality assurance of raw materials used also covers full traceability of batches on the suppliers’ side. KRAIBURG TPE’s materials also comply with REACH and RoHS requirements.

Press release

In addition, the THERMOLAST® M portfolio is listed in FDA Drug Master Files (DMF) to document its formulation in accordance with a mandatory change control procedure. KRAIBURG TPE further ensures alignment with the new VDI 2017 that the manufacturing processes are also included in the change control management system and the original formulation of such a compound will remain available in parallel with the new type for minimum 24 months after a possible change or withdrawal notification. This gives customers in the healthcare, pharmaceutical, medical and diagnostic industries the maximum controlled quality and supply security for the TPE medical compounds used.

The whole product range comprises compounds of different degrees of hardness, which can easily be sterilized using all common procedures such as ethylene oxide (EtO), hot steam, gamma or electron radiation. Along with standard compounds for enhanced grip and slip resistance, types providing optimized adhesion to technical thermoplastics such as polyesters and polyamides are available. There are also THERMOLAST® M compounds available that provide the necessary translucency and high transparency for visual inspections that are critical for treatment in medical applications, as well as special oil-free types of compounds and specific compounds for sealing applications.

About KRAIBURG TPE

KRAIBURG TPE (www.kraiburg-tpe.com) is a global manufacturer of thermoplastic elastomers. From its beginning in 2001 as subsidiary of the historical KRAIBURG Group founded in 1947, KRAIBURG TPE has pioneered in TPE compounds, today being the competence leader in this industry. With production sites in Germany, the US, and Malaysia the company offers a broad range of compounds for applications in the automotive, industrial, consumer, and for the strictly regulated medical sectors. The established THERMOLAST®, COPEC®, HIPEX®, and For Tec E® product lines are processed by injection molding or extrusion and provide

Press release

numerous processing and product design advantages to manufacturers. KRAIBURG TPE features innovative capabilities as well as true global customer orientation, customized product solutions and reliable service. The company is certified to ISO 50001 at its headquarters in Germany and holds ISO 9001 and ISO 14001 certifications at all global sites. In 2018, KRAIBURG TPE, with over 640 worldwide employees, generated sales of 189 million euros.

KRAIBURG TPE's thermoplastic elastomers in the THERMOLAST® M family meet the new VDI 2017 guideline that for the first time regulates the basic characteristics profile of medical grade plastics for medical products – from the raw materials permitted through to change control management. (Image: © 2019 KRAIBURG TPE)

Press release

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